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10/806,828	03/22/2004	Svava Maria Atladottir	ACS-64880 (4171DX)	4223

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EXAMINER

HOUSTON, ELIZABETH

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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/806,828
Filing Date: March 22, 2004
Appellant(s): ATLADOTTIR ET AL.

Gunther O. Hanke
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/04/10 appealing from the Office action mailed 11/06/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-15, 38, 40-42.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,827,321	ROUBIN	10-1998
6,251,136	GURUWAIYA	06-2001
WO 99/36002	VARDI	07-1999

(9) Grounds of Rejection

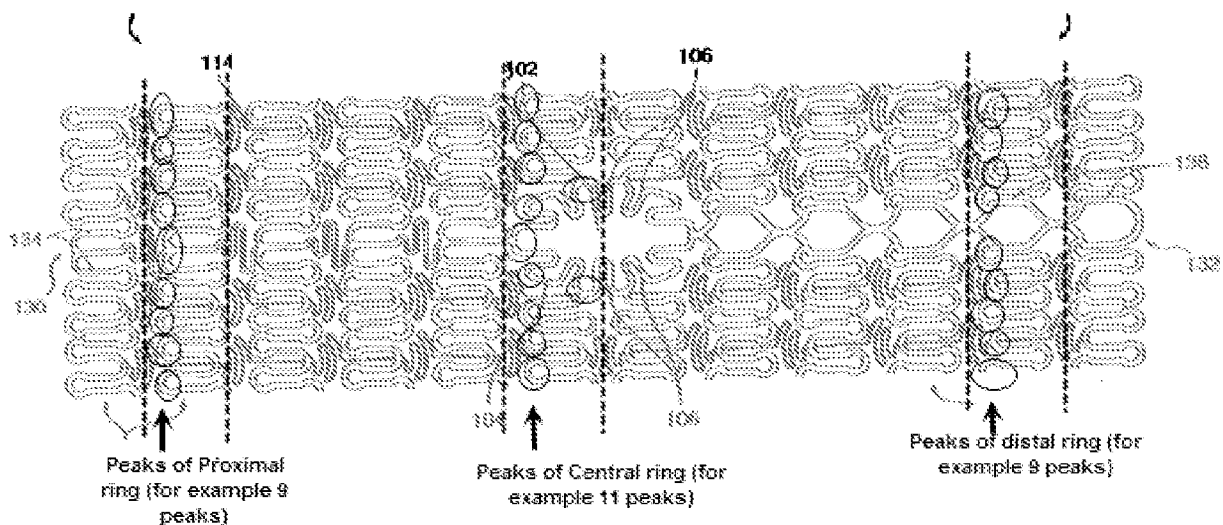
The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vardi (WO99/36002).

Vardi discloses a self-expanding stent (p12:1122-23) (Fig. 10) for treating a bifurcated vessel having a main vessel and a side branch vessel (see Fig. 1), comprising: a cylindrical body having a central longitudinal axis, wherein such cylindrical body is defined by a plurality of rings (for example 112, 122) spaced along such axis and wherein each ring is centered about such axis, adjacent rings being connected by links (114), and the cylindrical body having an unexpanded state and an expanded state; the cylindrical body having a proximal section (for example 110), a distal section (for example 120), and a central section (for example 102), each such section being

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defined by selected rings of said plurality of rings; a number of first peaks in each of the rings of the central section differing from a number of first peaks in each of the rings of the proximal section and the distal section(see below) to thereby provide additional material for apposing a side branch vessel; and the first peaks of the rings of the central section being configured to flare radially outwardly into an opening to the side branch vessel contacting the luminal wall of the side branch vessel and into at least a portion of the side branch vessel (for example Fig. 9); wherein the cylindrical body self-expands from the unexpanded state to the expanded state.



Claim 2: wherein the rings of the proximal section have between four and twelve first peaks, the rings of the distal section have between four and twelve first peaks, and the rings of the central section have between five and fifteen first peaks (see above).

Claim 3: wherein the rings of the proximal section have seven first peaks, the rings of the distal section have six first peaks, and the rings of the central section have eight first peaks (see above). Claim 4: the number of first peaks in the ring(s) of the central section is greater than the number of first peaks in any of the rings in either the proximal

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section or the distal section (see above). Claim 5: the rings are connected by at least one links between adjacent rings (114). Claim 6: the tubular body has a distal opening (132), a proximal opening (130), and a central opening (102). Claim 7: the distal opening and the proximal opening are aligned along the stent longitudinal axis (see Fig. 10). Claim 8: the central opening is radially offset relative to the alignment of the distal opening and the proximal opening (see Fig. 10).

Claims 9, 10, 15, 38, 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi (WO99/36002) in view of Roubin (US 5,827,321).

Vardi discloses the invention as stated above including claim 42: the body is formed of a single hypotube (p4:ll15-16), but does not disclose that the self expanding stent is formed of a self expanding alloy or superelastic material that is nitinol.

Regarding claim 15: the central section will have a larger diameter than the proximal or distal ends since it expands outward radially. However, Roubin discloses that it is old and well known to use a shape memory superelastic metal alloy like nitinol to create a self-expanding stent. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the claimed material into the stent since a person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results, namely a material that provides self-expanding capabilities.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi in view of Roubin as applied to claim 1 and further in view of Guruwaiya (US 6,251,136).

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Modified Vardi discloses the invention substantially as claimed except for the layer of drug and the primer material. Guruwaiya discloses a stent coated with a primer layer, which readily adheres to the material of the stent and is in turn constructed to retain a layer of pharmacological agent (Col 2: L20-34). Guruwaiya discloses that it is well known to be beneficial to deliver drugs with stents to treat problems such as thrombosis or neointimal hyperplasia. Guruwaiya further discloses using a primer layer of a polymer that more readily carries and releases the drugs as a benefit to layering the drug directly to the stent material. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a drug layer into the bifurcated stent since it is an old and well known enhancement to be able to treat the tissue with drugs while at the same time providing the treatment of the stent. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a primer layer between the stent layer and the drug layer since the primer layer will more readily carry and release the drug that the stent material may not be able to carry and release.

(10) Response to Argument

GROUND I

The basis of appellant's argument is that Vardi does not disclose a self-expanding stent. Respectfully, appellant must have overlooked the citation in the rejection above pointing to Page 12, lines 22-23, which states "the subject stents may be self-expanding to conform to the shape of the vessel in which they are deployed, or

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they may be expanded utilizing balloon catheters...". More broadly, the entire paragraph starting at page 12, line 20 discusses the different manners in which the stent can be transformed to its expanded form which clearly does not limit the invention to only be a balloon expanded stent. The fact that the disclosure is directed toward a preferred embodiment of a balloon-expandable stent does not negate the fact that Vardi explicitly states that the stent can be self-expanding.

Appellant states that a balloon expandable stent can not be configured to flare radially outwardly as a self expanding stent would, but rather can only be configured to *be flared* radially outward since it requires force being applied by the balloon. Firstly, Appellant's arguments are directed to the stent flaring outwardly, while the claims are directed to "the peaks of the rings of the central section are configured to flare radially outwardly". Vardi clearly shows the peaks of the central section flared outwardly for example 38 in Fig. 9 and 106 in Fig. 13F and Page 11, Lines 3-18 which discusses how expandable portion 38 is expanded outward radially into the branch vessel. Secondly, appellant attempts to distinguish between a self-expanding stent that can be "configured to flare radially outwardly" and balloon expanded stent that would be "configured to be flared radially outwardly", examiner notes that it is irrelevant *how* the stent achieves its final shape as long as the final shape has the portions flared radially outwardly. In other words, the current claim does require that the central peaks flare by self-expansion but merely requires that they "be configured to flare radially outwardly". Thus there is no limitation as to *how* the flaring occurs. Finally, the appellant's entire argument distinguishing between a self expanding stent and a balloon expanding stent is moot in

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light of Vardi's teaching that the inventive stent can in fact be self-expanding (Page 12, lines 22-23.

Appellant goes on to argue that use of the terminology "first" to describe the peaks necessarily requires that the peaks have the same size, shape and orientation. Examiner strongly disagrees. The claim states a "number of first peaks in each of the rings differing from a number of first peaks in each of the rings of the proximal section and the distal section" thus requiring that the central portion has a different number of peaks in its rings than the proximal and distal section. The use of the term "first" is merely interpreted as an identifier that groups a number of the peaks together. It in no way limits the peaks in the grouping to have the same, size and/or orientation. This limitation is simply not stated nor is it implied anywhere in the claim

GROUND II

The Roubin reference was brought in to teach the use of specific material that is commonly used in self-expanding stents since the Vardi reference did not describe what material the self expanding stent was made of. Appellant argues that there is no suggestion that the structure of the Vardi reference would be capable of flaring radially outwardly. This argument is addressed above and is irrelevant to the issue of materials. Appellant further argues that Vardi teaches of such a complex mechanism (two balloons) in order to expand the stent and so there is no suggestion or teaching as to how such a complex system could be similarly achieved with self expanding material. Examiner respectfully disagrees. There are numerous patents that use self-expanding material to expand stents with flared portions at an ostium or branched vessel. By using

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shape memory, the second memorized configuration can be configured as desired, including having flared portions. Alternatively, there is nothing in the claim that requires the flared portion to be flared through self expansion. In other words while the stent can be self expanding (at least the tubular main branch portion) and made of nitinol, the flared portion could be further balloon expanded, which is also known in the art, without steering from the scope of the claim.

GROUND III

With respect to claims 11-14 as dependent from claim 1, appellant continues to argue the invalidity of the Vardi reference with respect to teaching a self expanding stent that has peaks in the central section that flared into the side branch vessel. As stated above with respect to Ground I, Vardi clearly discloses a self expanding stent (Page 12, line 20 - page 13, line2) that has peaks that flare into the side branch vessel (38, Fig. 9 or 106 Fig. 13F). Appellant continues the invalidity of the combination of Vardi and Roubin since there is no teaching how the self-expanding material would be incorporated. As stated above with respect to Ground II, it is old and well known in the art to incorporate shape memory material into a stents in order to form a desired expanded shape. Appellant states that the Guruwaiya reference does not overcome these shortcomings. Examiner respectfully agrees and points out that Guruwaiya is merely used to teach a coating on the stent. Since applicant did not point out any error with respect to the Guruwaiya reference, the combination is presumed to be proper.

(11) Related Proceeding(s) Appendix

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No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Elizabeth Houston

/Elizabeth Houston/
Examiner, Art Unit 3731

Conferees:

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731

Michael Milano
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